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09/919,395	07/31/2001	Robert D. Black	9099-6	3431

20792 7590 08/13/2003  
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EXAMINER

GABOR, OTILIA

ART UNIT PAPER NUMBER

2878

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/919,395

Applicant(s)

BLACK ET AL.

Examiner

Otilia Gabor

Art Unit

2878

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21, 22, 24-58 and 72-78 is/are allowed.
- 6) ☒ Claim(s) 1-20, 23, 59-70 and 79 is/are rejected.
- 7) ☒ Claim(s) 71 and 80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Response to Amendment***

1. The amendments filed 06/25/2003 have been entered.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 10, 11, 16-18, 23, 69, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenev et al. (U. S. Patent 6429444) in view of Jacobsen et al. (U. S. Patent 6165155).

Korenev discloses an apparatus and method for determining the dose of radiation that an item (food or medical) is exposed to in order to determine whether the dose is enough or too much for sterilization purposes. The device comprises:

- a source of radiation 10 to generate an electron beam to irradiate the object 30 which is positioned and moved on a conveyor belt 32
- a first array of detectors 40a disposed between the source of radiation and the item 30 to measure the radiation coming from the source 10
- a second and third array of detectors 40b and 40c disposed after the plurality of items 30 to detect the radiation that passed through the items (the items are packaged in a container). The sensors are configured to measure the changes in the radiation received by a change of their operational parameters.
- a processor 54 such as a computer which accepts the data from the sensors (the signals are amplified and digitized) and by comparing the strength of the radiation before entering and after leaving the items determines the dose of radiation the items are subjected to. The processor also compares the measured dose information with preselected dose requirements and based on those finding the processor adjusts the parameters (such as time or position that the item is under irradiation) necessary to increase or decrease the dosage.

The items to be sterilized could be but are not limited to any food items and/or medical objects. The items 30 (at least 2 shown in Fig.1) are positioned side by side on the belt and are packages which hold the individual items to be irradiated (thus the plurality of objects are grouped in packages which are separately irradiated by different sensor arrays 40b and 40c as claimed in claim 18). Also since each package could contain any type of items (the invention does not specify that each item 30 contains the same type of product) and since each item 30 is irradiated by a different sensor array (40b and

40c) each of the arrays responds to the particular radiation dosage through the particular item (claim 25).

Korenev fails to use a wireless connection between the sensors and the remote processor, however one of ordinary skill in the art would have been motivated to use the wireless connection as disclosed by Jacobsen et al. since it is well known in the art that such a connection is much more efficient when remote communication is needed between the sensors and the main processor, for it removes the need for cables.

5. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenev et al. and Jacobsen et al. (U. S. Patent 6165155).

Regarding claims 13-15 Korenev does not specify the dose range, however this constitutes only a matter of design choice since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Regarding claim 12 it would have been obvious to one of ordinary step at the time the invention was made the repeat the transmitting and dosage determining step in order to increase the accuracy of the dosage level reading.

6. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenev et al. and Jacobsen et al. and further in view of Thomson et al. (U. S. Patent 5117113).

Korenev does not limit the type of sensors to be used in determining the dose of

irradiation (see Col. 4, line 42-43 and Col. 5, lines 11-20) and as such any one type that is used as a dosimeter can be used. Thus, one of ordinary skill in the art would have been motivated to use sensor as disclosed by Thomson. Thomson discloses a dosimeter including a MOSFET device whereby by measuring the difference in the threshold voltages (the test mode or the pre-radiation and the actual irradiation) of the transistors the radiation dosage is calculated. Any change in the threshold voltage is indicative of the radiation dosage.

7. Claims 7, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenev et al. and Jacobsen et al. and further in view of Fujiuchi et al. (U. S. Patent 5656998).

Korenev does not limit the type of sensors to be used in determining the dose of irradiation and as such any one type that is used as a dosimeter can be used. Thus, one of ordinary skill in the art would have been motivated to use sensor as disclosed by Fujiuchi et al. Fujiuchi et al. discloses a sensor including an electronic circuit comprised of a resistor connected to a capacitor and an inductor whereby the dosage of radiation is measured by the change in the Q-factor which is indicative of the change in the resonant frequency.

8. Claims 9, 59-64, 67, 68, 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenev et al. and Jacobsen et al. and Fujiuchi et al. and further in view of Kronenberg et al. (U. S. Patent 5477050).

Korenev does not limit the type of sensors to be used in determining the

dose of irradiation and as such any one type that is used as a dosimeter can be used. Thus, one of ordinary skill in the art would have been motivated to use sensor as disclosed by Kronenberg et al. Kronenberg et al. discloses a dosimeter comprised of a circuit with a resistor and capacitor, a coil (inductance) and a transistor where the capacitor is comprised of two parallel plates having a dielectric in between. The dose of incident radiation is measured by the change in the dielectric material.

9. Claims 19, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenev et al. and Jacobsen et al. as applied to claim 19 and 43 and Korenev et al. and Jacobsen et al. and Fujiuchi et al. and Kronenberg et al. as applied to claim 65 above, and further in view of Thomson (U. S. Patent 4484076).

Korenev does not limit the type of sensors to be used in determining the dose of irradiation and as such any one type that is used as a dosimeter can be used. Thus, one of ordinary skill in the art would have been motivated to use sensor as disclosed by Thomson. Thomson discloses a dosimeter where the radiation dose is measured by the change in the Hfe of a bipolar transistor included in the tank circuit of the sensor.

10. Claims 20 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenev et al. and Jacobsen et al. as applied to claims 20, 44 and Korenev et al. and Jacobsen et al. and Fujiuchi et al. and Kronenberg et al. as applied to claim 66 and further in view of Ishikawa et al. (U. S. Patent 6398710).

Korenev does not limit the type of sensors to be used in determining the

dose of irradiation and as such any one type that is used as a dosimeter can be used. Thus, one of ordinary skill in the art would have been motivated to use sensor as disclosed by Ishikawa et al. Ishikawa et al. discloses a dosimeter where the radiation dosage is measured by the change in the leakage current of a diode in the circuit.

### ***Allowable Subject Matter***

11. Claims 21, 22, 24-58, 72-78 are allowed.
12. Claims 71, 80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
13. The following is a statement of reasons for the indication of allowable subject matter: The amendments made by the Applicant to more clearly define the invention, namely, that the sensor is passively powered through the wireless reader which is operably controlled by the computer program of the controller, overcome the prior art rejections where the sensor is not passively powered and thus render the claims allowable. Claim 34 contains allowable subject matter as indicated in detail in the previous Office Action.

### ***Response to Arguments***

14. Applicant's arguments filed 06/25/2003 have been fully considered but they are not persuasive. The Applicant's arguments regarding the passively powered sensors through the wireless reader are persuasive and thus the claims containing these



limitations are accordingly allowed in the paragraphs above. Another argument presented by the Applicant is that the wireless link of Jacobsen cannot be used in the harsh environment disclosed by Korenev because the wireless link of Jacobsen is not used in the field of radiation measurement. However this argument is not persuasive because 1) Jacobsen uses the conventional wireless link 48 in the case where the patient wants to remotely monitor and transfer stored data and thus does not want to be in the vicinity of the measuring or monitoring field and 2) since these wireless data transfer links are conventional and are used to remotely monitor measurements, data input, sensing, etc., it is only logical to use them more often in harsh rather than mild environments. Another argument presented by the Applicant is that the controller of Jacobsen is powered by a battery and thus it cannot passively power the sensor. This argument is persuasive only for the embodiments that incorporate passive powering of the sensors through the wireless link controlled by the controller (i.e., independent claims 21, 45). Having only the limitation that the sensor is a passive dosimeter where the wireless reader receives data from the sensor without specifying that the sensor is in fact passively powered, does not overcome the rejections as applied in detail above and in the previous Office Action. Thus claim 1, though includes a passive sensor, does not overcome the rejections as applied in detail above. Regarding independent claims 1, 23 and 59, the Applicant argues that because they now contain the previously indicated allowable subject matter ("single use disposable dosimeter"), they are now in condition of allowance. However, the Examiner also indicated that these claims would be allowable only if they included all the limitations of the base claim as well as any

intervening claims. The Examiner also indicated the exact reasons why these limitations would make the claims allowable, one of those reasons being that the sensors as claimed were single use and disposable, meaning that they are not only used only once per measurement but also that they are removable from their measuring positions. In response to the Examiner's indication of allowable subject matter as well as the reasoning behind it, the Applicant responded by 1) rewriting the base claim to broaden the scope of the claim by removing the limitations of the base claim and the intervening claims (see claim 23), and 2) removed part of the allowable subject matter phrase, i.e., instead of using "single use disposable dosimeter" it broadened the phrase to only read "single use" (see claims 1, 59) and 3) introduced a new definition as to what "single use disposable" will mean in the present application. Because of these changes, the indication of allowable subject matter as recorded in the previous Office Action is no longer valid. Thus, the claims still stand rejected as indicated in detail above.

### ***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not


mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Otilia Gabor whose telephone number is 703-305-0384. The examiner can normally be reached on Monday-Friday between 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 703-308-4852. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

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August 8, 2003

  
**DAVID PORTA**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 2800**